REMARKS

This Response is submitted in reply to the non-final Office Action mailed on November 20, 2008. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-626 on the account statement.

Claims 1-3 and 5-13 are pending in the application. Claim 4 was previously canceled. In the Office Action, Claim 12 is rejected to under 37 C.F.R. 1.75(c); Claim 5 is rejected to under 35 U.S.C. §112; and Claims 1-3 and 5-13 are rejected to under 35 U.S.C. §103. In response, Applicants amend Claims 1, 5, 7, 10 and 11 and cancel Claims 3 and 12. The amendments do not add new matter and are supported in the specification at page 5, lines 7-8 and original Claim 3. In view of the amendments and for at least the reasons provided below, Applicants respectfully request that the rejections be withdrawn.

In the Office Action, Claim 12 is rejected to under 37 C.F.R. 1.75(c), as being improper dependent form for failing to further limit the subject matter of a previous claim. In response, Applicants cancel Claim 12. Applicants request therefore that the objection to Claim 12 be withdrawn.

In the Office Action, Claim 5 is rejected to under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5, which previously depended from canceled Claim 4, has been amended to depend from Claim 1. Applicants request therefore, that the rejection of Claim 5 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-3 and 5-13 are rejected to under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,475,539 to DeWille, et al. ("*DeWille*") in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) ("*PURAC*"). Amended independent Claim 1 recites, in part, a nutritional infant formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula directly acidified. Independent Claim 7 recites, in part, a method of preparing a nutritional infant formula comprising directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid.

Independent Claims 10 and 11 recite, in part, a method comprising directly acidifying a nutritional infant formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid. Applicants submit that the cited references fail to disclose or suggest every element of the present claims.

DeWille fails to disclose or suggest the use of L(+)- lactic acid in a nutritional infant formula as required, in part, by the present claims. Though *DeWille* does teach use of general lactic acid, *DeWille* fails to teach, suggest, or even mention specific use of L(+)- lactic acid as required by the claims. The Office Action admits the same. See, Office Action, page 5, ¶13. The Office Action further admits that *DeWille* is silent as to the formula being an infant formula. *Id.* Moreover, simply disclosing the use of lactic acid does not make it obvious to one skilled in the art that this disclosure refers to L(+)-lactic acid. Beside L(+)- lactic acid, general "lactic acid" could refer, for example, to a racemic of lactic acid and another acid, potassium lactate, sodium lactate, D(-)- lactate, DL-lactic acid, or D(-) lactic acid.

The Office Action asserts, however, that it would have been obvious to use L(+) lactic acid, cited in the product data sheet of *PURAC*, to acidify the formula in *DeWille* and that Applicants are doing no more than using a know compound for its intended use in order to provide a predictable result of acidifying a foodstuff. See, Office Action, page 5, ¶15. Applicants respectfully disagree. Simply citing a product data sheet (*PURAC*) that publishes information for two of many different kinds "lactic acid" in no way remedies the deficiency of *DeWille*. Just disclosing analytical information regarding two lactic acid ingredients does not provide one skilled in the art reason to use the specific lactic acid disclosed in *PURAC* as the general lactic acid taught in *DeWille*. Moreover, nothing in *PURAC* teaches or suggests that the lactic acid taught therein is safe for use with infants as is required by the nutritional formula of the present claims.

Furthermore, if the Patent Office attempted to assert that it would be obvious to one skilled in the art to use L(+) lactic acid for infant formulas, this assertion would run contrary to art recited below. For example, *WHO* teaches acidifying with general DL-lactic acid and not direct acidification with a specific L(+)-lactic acid. See, *WHO*, page 5. DL-lactic acid is a racemic mixture of L(+) and D(-) lactic acid forms. As a result, because the experiments in *WHO* show that infants had difficulty utilizing DL and D(-) lactic acids, infants inherently had

difficulty utilizing both L(+) and D(-) lactic acid forms. Therefore, no part of *WHO* teaches that infants can positively utilize L(+) lactic acid. Instead, based on the negative results of the racemic DL lactic acid, *WHO* actually teaches away from using L(+) lactic acid in nutritional compositions. Therefore, even other references cited herein establish that one skilled in the art would have no reason to use L(+) lactic acid from *PURAC* for the general lactic acid taught in *DeWille*.

Accordingly, Applicants respectfully submit that *DeWille* in view of *PURAC* is deficient with respect to the present claims.

In the Office Action, Claims 1, 3-6 and 12 rejected to under 35 U.S.C. §103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) ("*Schwartz*") in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) ("*WHO*") with additional evidence provided by Wong, et al. (Wong, Nobel P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag) ("*Wong*"). Further, in the Office Action, Claims 1-3 and 5-12 rejected to under 35 U.S.C. §103(a) as being unpatentable over *Schwartz* in view of *PURAC* with additional evidence provided by *Wong*. Applicants respectfully submit that the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims.

Schwartz fails to disclose or suggest an infant formula directly acidified with L(+)-lactic acid as required, in part, by the present claims. The Office Action admits the same. See, Office Action, page 7, ¶21. *WHO* fails to remedy this deficiency with regard to an L(+)-lactic acid because (a) *WHO* fails to disclose or suggest an infant formula for direct acidification using L(+)-lactic acid and, as stated above, (b) *WHO* fails to disclose or suggest using L(+)-lactic acid in nutritional infant formulas and actually teaches away from using L(+)-lactic acid in nutritional formulas. Moreover, *Wong* also fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 8, ¶28. Finally, *PURAC* is also deficient because it fails to teach use of L(+) lactic acid in infant formulas. Moreover, as explained above, one skilled in the art would have no reason to

combine *PURAC* with *Schwartz* based on the teachings of *WHO* (teaches away from L(+) lactic acid use in infants) and *PURAC's* failure to disclose, suggest or even mention application of its product to infant formulas.

In response, The Office Action asserts that, in view of *WHO*, one or ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in infant formula because *WHO* teaches away from DL lactic acid usage and therefore teaches away from the inclusion of D(-) lactic acid, not the L(+) lactic acid of the present claims. See, Office Action, pages 10-11, ¶42. Applicants disagree and submit that even though *WHO* teaches away from DL lactic acid usage, there is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. As stated above, what is indeed known is that DL-lactic acid is a racemic mixture of L(+) and D(-) lactic acid forms and *WHO* teaches that infants had difficulty utilizing DL and D(-) lactic acids, not the D(-) portion of DL lactic acids. Therefore, Applicants submit that the Examiner is making conclusions without citing evidence from the references in question. Moreover, the vast majority of *WHO* is devoted to non-human mammalian testing. On the other hand, *WHO* admits that human studies regarding lactate load are not available and that the increase in the urinary excretion of either form of lactic acid [L(+) of D(-)] indicated that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. See, *WHO*, page 4. Accordingly, *WHO* provides little or no evidence that either form of lactic acid performs any better than the other in infants.

Therefore, the combination of *Schwarz* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims. Moreover, the combination of *Schwartz* in view of *PURAC* and *Wong* fails to disclose or suggest every element of the present claims.

In the Office Action, Claims 1, 3 and 5-12 rejected to under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,212,893 to Takahata ("*Takahata*") in view of *WHO* with additional evidence provided by *Wong*. Applicants respectfully submit they the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims.

Takahata fails to disclose or suggest an infant formula directly acidified with L(+)-lactic acid as required by the present claims. The Office Action admits the same. See, Office Action, page 9, ¶36. As stated previously, *WHO* fails to remedy this deficiency with regard to L(+)-lactic acid because (a) *WHO* fails to disclose or suggest a formula for direct acidification using

L(+)-lactic acid and (b) *WHO* fails to disclose or suggest using L(+)-lactic acid in nutritional formulas and actually teaches away from using L(+)-lactic acid in nutritional formulas. Moreover, *Wong* fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 9, ¶35.

In response, the Office Action again makes the same assertions regarding *WHO* as it did for the above rejections. Specifically, the Office Action notes that because *WHO* specifically states neither D(-)- nor DL lactic acid should be used in infant foods, one of ordinary skill would recognize that L-(+) lactic acid is the obvious choice for inclusion in the infant formula. Applicants, again, disagree with these assertions for at least the reasons discussed previously.

Therefore, the combination of *Takahata* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections of Claims 1-3 and 5-13 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit and early allowance of same.

Respectfully submitted,

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